

Application Serial No. 09/764,630  
Response dated April 13, 2005  
Reply to Office Action dated January 13, 2005

### **REMARKS**

Claims 1, 3-6, and 8-13 are pending. Claim 13 has been withdrawn from consideration by the Examiner. Claims 1, 3-6, and 8-12 have been rejected. Claims 1, 5, 8, and 12 have been amended. In view of the amendments to the claims and the discussion below, Applicants now believe that the application is condition for allowance.

### **Elections/Restrictions**

The Examiner has withdrawn claim 13 from consideration as being directed to a nonelected invention. In particular, the Examiner states that newly submitted claim 13 is directed to an invention that is independent or distinct from the originally claimed invention because it recites a rearward extension with a knurled interior cavity, whereas the claims originally examined on the merits recite an extension that is enveloped by a coupling mechanism. Applicants respectfully request a reconsideration of the withdrawal of claim 13. In particular, Applicants note that independent claim 13 finds support in original claim 7, which was previously cancelled in favor of new claim 13. Thus, since the substance of claim 13 was present in the claims as originally examined on the merits, Applicants submit that new claim 13 would not require any further searching beyond that which has been and will be performed by the Examiner regarding claim 7.

### **Claim Rejections 35 U.S.C. § 112**

Claims 5, 6, and 8-11 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

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subject matter which Applicants regard as the invention. In particular, the Examiner has rejected 5 and 8 as being incomplete for omitting essential elements, such omission amounting to a gap between the elements (claim 6 depends from claim 5; claims 9-11 depend ultimately from claim 8). The Examiner states that the omitted elements are the injector in claim 5, which has mating sections to align with syringe mating sections, and in claim 8, the coupling mechanism on the plunger drive ram. In response, Applicants have presently amended claim 5 to recite injector mating sections on an injector. Further, Applicants have presently amended claim 8 to recite a coupling mechanism. In view of the amendments to the claims, Applicants respectfully request a withdrawal of the rejection of claims 5, 6, and 8-11 under 35 U.S.C. § 112, second paragraph.

**Claim Rejections 35 U.S.C. § 102**

**Nightingale (U.S. Patent No. 3,747,479)**

The Examiner has rejected claims 1, 3-6, and 12 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,747,479, issued to Nightingale. Nightingale had been used as a rejection of the same claims in the previous Office Action. In response thereto, Applicants had argued that Nightingale did not disclose a rearward extension that is capable of being within an area enveloped by a coupling mechanism. In the present Office Action, the Examiner disagrees and states that Nightingale discloses a "rearwardly-facing drive ram engaging coupling element 72," and that this "extension from the plunger does have [the] capability [of being within an

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area enveloped by a coupling mechanism] due to its elongated structure." Applicants respectfully disagree.

Applicants note that claim 1 recites that the rearwardly facing extension is "knurled at least along the portion of said extension adapted to be within an area enveloped by a coupling mechanism," and that the extension "does not extend outside of the cylindrical barrel in at least one position of the plunger." Claim 12 recites that "no two adjacent transverse cross-sections of said rearwardly facing extension exhibit discontinuity . . . along the portion . . . adapted to be within the area enveloped by a coupling mechanism."

Nightingale is directed to a piston assembly that is used in syringes and stopcocks. In particular, Figure 7, which is pointed to by the Examiner in rejecting claims 1 and 12, is of a syringe including the piston assembly. As can be seen from that Figure, the threaded sleeve 72 (which the Examiner considers to be a "rearwardly-facing drive ram engaging coupling element") is already coupled to a mechanism to move the plunger within the syringe barrel: an operating bar 79 and mandrel 73, which extend through the threaded sleeve 72. Applicant submits that this operating bar and mandrel are not a drive ram, as is found on injectors such as those described in the present application. Thus, Applicant submits that the threaded sleeve 72 cannot be a "drive ram engaging coupling element" as recited by claim 1.

Even if one were to assume, for the sake of argument, that the operating bar and mandrel form a drive ram (which Applicants submits they do not), Applicants

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assert that the knurled portion of the threaded sleeve 72 is not "adapted to be within an area enveloped by a coupling mechanism." This is because there is no enveloping coupling mechanism disclosed by Nightingale. Rather, as is clear from Fig. 7, there is already a mechanism coupled to the extension in Nightingale: the operating bar 79 and mandrel 73. If one were to envelope the knurled area of the rearward facing extension of Nightingale, one would block off the opening that is used to receive the operating bar 79 and mandrel 73. In such a configuration, elements of the apparatus would have to be removed from Nightingale's disclosure, and the function of the apparatus of Nightingale would be destroyed.

Further, again referring to Fig. 7 of Nightingale, even if one were to assume, for the sake of argument, that the extension of Nightingale could be enveloped with a coupling mechanism (which Applicants submit it could not, since to do so would ignore elements of Nightingale and destroy the function of Nightingale), Applicants assert that the extension could not then be received within the barrel of the syringe shown in Fig. 7 (due to the small clearance between the threaded sleeve and syringe barrel). In such a configuration then, Nightingale's extension would need to be lengthened so that at least a portion of the extension would remain outside the syringe barrel in all positions of the plunger – otherwise, there would be no way to envelop the coupling mechanism. However if thus modified, Nightingale would not satisfy the limitation in claims 1 and 12 that the rearwardly facing extension "does not extend outside of said cylindrical barrel in at least one position of said plunger."

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Also, even if one were to assume that the extension of Nightingale could be enveloped with a coupling mechanism (which Applicants submit it could not), Applicants assert that the extension would include discontinuities in adjacent cross-sections in the area enveloped by the coupling mechanism, considering that the knurled surface would be enveloped within that area. Thus, Nightingale would not satisfy the limitation that "no two adjacent transverse cross-sections of said rearwardly facing extension exhibit discontinuity . . . along the portion . . . adapted to be within the area enveloped by a coupling mechanism" as recited by claim 12.

However, the Examiner makes such assumptions, regarding Nightingale, by stating that claims 1 and 12 do not positively recite a coupling mechanism (they only recite that the extension is adapted to be enveloped by a coupling mechanism). And according to the Examiner, the threaded sleeve 72 could be so adapted due to its elongated shape. However, Applicants submit that even though neither claim 1 nor claim 12 positively recite the coupling mechanism, the absence of such a recitation does not give the Examiner license to engage in a wholesale modification of the components disclosed as Nightingale in a manner that eliminates elements of the apparatus of Nightingale and destroys the function of the apparatus of Nightingale relative to those elements. In view of the above, Applicants respectfully request a withdrawal of the rejection of claims 1, 3-6, and 12 under 35 U.S.C. § 102(b) as anticipated by Nightingale.

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**Reilly (U.S. Patent No. 4,677,980)**

The Examiner has further rejected claims 1, 3-6, and 8-11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,677,980, issued to Reilly. Applicants respectfully disagree.

Regarding claims 1 and 3-6, Applicants note that independent claim 1 recites that the rearwardly facing extension is knurled at least "along the portion of said extension adapted to be within the area enveloped by a coupling mechanism." The Examiner states that the common definition of a knurl is "a protuberance, as a knob or knot," or "one of a series of small ridges." Applicant agrees with the Examiner that knurls can be a "series of small ridges," and that such knurls are disclosed in the present application (see at least Figs. 4A-4C of the present application). As can be seen in the application, these sorts of knurls provides extra friction to facilitate gripping between two surfaces, but do not form any interlocking engagement between the two surfaces. Thus, Applicants have further amended claim 1 to recite the knurled surface as being "a series of ridges or grooves." Applicants submit that the apparatus disclosed in Reilly does not satisfy this limitation.

Only in Figs. 17 and 20, does Reilly show a coupling mechanism enveloping a rearwardly facing extension. However, Applicants submit that the rearward facing extension of Fig. 20 is not knurled, in that it does not include a series of ridges or grooves, as recited by claim 1. Neither does the structure of Fig. 17 show ridges or grooves. Referring to Fig. 17 and the disclosure at column 10, lines 4-31,

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Applicants submit that the structures shown in Fig. 17 on the extension are a plurality of raised screw-type threads (160), which define a plurality of incline channels (162) therebetween. The screw-type threads (160) are designed to interact with a hook member (170), which is fixedly mounted on the right angle member of a hook assembly (166) of the coupling mechanism (also shown in Figs. 18 and 19). In use, as the drive mechanism, including the coupling mechanism, is advanced by the drive piston, the hook-shaped members (170) enter respective one of the channels (162) between the screw threads (160). As this happens, the hook members pass through the channels. Eventually, the outer ends of the hook assemblies (166) engage the extension on the plunger. In other words, the configuration of hooks on the coupling mechanism and threads on the extension engage to form an interlocking engagement to hold the syringe plunger to the drive ram. This sort of interlocking engagement is completely different from the function provided by knurls. Thus, knurls are not described in the text of Reilly, nor shown in the Figures. Applicants thus submit that Reilly fails to disclose each and every claimed element of the present application in claim 1, as presently amended. Applicants thus submit that claim 1 is not anticipated by Reilly. Since claim 1 is not anticipated, Applicants further submit that dependent claims 3-6 are also not anticipated by Reilly. Applicants therefore respectfully request a withdrawal of the rejection of claims 1 and 3-6 as being anticipated by Reilly under 35 U.S.C. § 102(b).

Regarding claims 8-11, Applicants note that independent claim 8 has been presently amended to recite that "no two adjacent transverse cross-sections of

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said rearwardly facing extension exhibit discontinuity in area when compared to one another along the portion of said extension adapted to be within the area enveloped by said coupling mechanism." Applicants note that all embodiments of Reilly, including rearward extensions enveloped by a coupling mechanism, include some discontinuity between two adjacent cross-sections within the area enveloped. Applicants thus submit that claim 8 is not anticipated by Reilly. Since claim 8 is not anticipated, Applicants further submit that dependent claims 9-11 are also not anticipated by Reilly. Applicants therefore respectfully request a withdrawal of the rejection of claims 8-11 as being anticipated by Reilly under 35 U.S.C. § 102(b).

**Densmore (U.S. Patent No. 5,007,904)**

The Examiner has further rejected claims 1 and 3-6 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,007,904, issued to Densmore. Applicants respectfully disagree.

As noted above with respect to the rejection of claim 1 under Nightingale, claim 1, as presently amended, recites that the extension is "knurled at least along the portion . . . adapted to be within an area enveloped by a coupling mechanism." Like Nightingale, Applicants submit that Densmore does not disclose a coupling element on a plunger that is enveloped by a coupling mechanism. Rather, Densmore shows a rearward facing extension that envelopes a coupling mechanism. Applicants thus submit that Densmore fails to disclose each and every claimed element of the present application in claim 1, as presently amended. Applicants thus submit that claim 1 is not



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anticipated by Densmore. Since claim 1 is not anticipated, Applicants further submit that dependent claims 3-6 are also not anticipated by Densmore. Applicants therefore respectfully request a withdrawal of the rejection of claims 1 and 3-6 as being anticipated by Densmore under 35 U.S.C. § 102(b).

**Neer (U.S. Patent No. 5,300,031)**

The Examiner has further rejected claims 1, 3-6, and 8-11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,300,031, issued to Neer. Applicants respectfully disagree.

Applicants note that claim 1 recites a rearwardly facing extension "wherein said rearwardly facing extension is knurled," with the knurls "being a series of ridges or grooves." Applicants submit that it is clear from the figures of Neer, et al., that the T-shaped button located at the end of the plunger drive ram is not knurled, as that term is used in the present application. As described above, Applicants submit it is clear from the text and drawings of the present application that knurls are a series of ridges or grooves that are used to impart friction to aid one element gripping to another. Thus, Applicants submit that the Neer reference fails to disclose each and every claimed element of the present application in claim 1. Applicants thus submit that claim 1 is not anticipated by the Neer reference. Since claim 1 is not anticipated, Applicants further submit that dependent claims 3-6 are also not anticipated by Neer. Applicants therefore respectfully request a withdrawal of the rejection of claims 1 and 3-6 as anticipated by Neer under 35 U.S.C. § 102(b).

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Applicants note that claim 8 has been presently amended to recite a rearwardly facing extension "wherein no two adjacent transverse cross-sections of said rearwardly facing extension exhibit discontinuity in area when compared to one another along the portion of said extension adapted to be within the area enveloped by a coupling mechanism." Regarding "the area enveloped by a coupling mechanism" recited in the claims, Applicants note that the rearward facing element of Neer includes a T- or mushroom-shaped button located at the end of the plunger drive ram (see reference 96 in Fig. 4 of Neer). As can be seen, this button includes an extension protruding from the rearward face of the syringe plunger, topped by a cap. Further, Applicants submit that it is clear from at least Figs. 11 and 12 of Neer that the T-shaped button is enveloped within the area encompassed by two jaws 114, that extend from a point near pivot pins 115 to a point near surfaces 120. Thus, the area enveloped by the jaws includes both the button 98 and the extension 96. Applicants further note that such a coupling element would exhibit discontinuity in area in adjacent transverse cross-sections, in that a cross-section taken at the cap of the button would be of much greater diameter than an adjacent cross-section taken along the extension protruding from the rearward face of the syringe plunger. Thus, Applicants submit that the Neer reference fails to disclose each and every claimed element of the present application in claim 8, as presently amended. Applicants thus submit that claim 8 is not anticipated by Neer. Since claim 8 is not anticipated, Applicants further submit that dependent claims 9-11 are also not anticipated by Neer. Applicants therefore respectfully request

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a withdrawal of a rejection of claims 8-11 as anticipated by Neer under 35 U.S.C.

§ 102(b).

**Conclusion:**

For the foregoing reasons, it is submitted that all claims are patentable and a Notice of Allowance is respectfully requested.

It is believed that no fee is due. If, however, any additional fee or surcharges are deemed due, please charge same or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

Wood, Herron & Evans, L.L.P.

By:   
David E. Jefferies, Reg. No. 46,800

Wood, Herron & Evans, L.L.P.  
2700 Carew Tower  
Cincinnati, Ohio 45202  
(513) 241-2324 (telephone)  
(513) 241-6234 (facsimile)  
[djefferies@whepatent.com](mailto:djefferies@whepatent.com) (email)

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